

REMARKS

Claims 1-15 were originally filed in the application. Claims 16-21 were added in amendments. Claims 2-4 and 9 were previously withdrawn from consideration. Claims 1, 5-8 and 10-21 are rejected in the *final* Office Action. Claims 1, 5-8, and 10-21 are pending. Reconsideration of claims 1, 5-8, and 10-21 is respectfully requested.

Claims 1 and 5-8.

In the Office Action, claims 1 and 5-8 are rejected under 35 USC § 103(a) as being unpatentable over Feller, Jr. et al. (4,362,156), in view of (1) Wenstrom, Jr., (2) Hildwein, et al., (3) Wellner, et al., (4) Ternamian, or (4) Bedi. Claims 5-8 depend from claim 1.

Claim 1 has been amended herein to recite “wherein cells grow into engagement with said texture during the bodily process of healing the puncture wound.” Support for this amendment is found on p. 6, ln.17 – p. 7, ln. 1 of Applicant’s specification which reads:

An additional important function of texture 22 is that the skin 24 (microplast) surrounding interface 18 will grow in an attempt to close or heal the hole (puncture)through which interface 18 and cannula 20 are inserted **such that the cells will grow into engagement with the greater surface area of the interface caused by the texture in an attempt to close the puncture wound caused when the catheter was inserted.** This interface between the cells of skin 24 and texture 22 of interface 18 will help deter interface 18 from moving in and out of skin 24 when the patient moves through activity. In this way, the possibility of infection causing germs from entering the puncture wound through skin 24 and the blood stream within vein 26 from the portion of interface 18 extending outside of skin 24 is greatly reduced. Such reduction in the possibility of the introduction of

bacteria or fungus into the body is significant in the reduction of serous infection possibilities inherent in the use of the venous catheter. . .

(emphasis added). Claims 5-8 depend from claim 1.

None of the cited references disclose an interface including a texture to allow cell growth into engagement with the texture during the bodily wound healing process. In the Office action, the Examiner admits that the primary reference, Feller, Jr. et al., ***does not disclose*** texture on the interface as required by Applicant's claim 1. Since the Feller, Jr. et al. reference does not disclose texture, it cannot disclose texture to allow cell growth therein.

It is asserted in the *final* Office action that the use of texture on interfaces is conventional in the art as evidenced by the teachings of (1) Wenstrom, Jr., (2) Hildwein, et al., (3) Wellner, et al., (4) Ternamian, or (4) Bedi. Although Applicant respectfully disagrees that these references evidence that the use of texture is conventional in the art, none of these references disclose texture to allow cell growth therein.

The above cited secondary references disclose various types of constructions used to insert and secure the insertion apparatus to the surrounding tissue, ensuring the stability of the apparatus while conducting ***surgical procedures***. As surgical devices, they are not intended to remain in contact with the bodily tissue for a time sufficient for cell growth and engagement therein. Moreover, their constructions are designed for insertion of the apparatus and are too aggressive for cell growth therein.

Applicant's device as recited in claims 1, 5-8, and 19-21, in contrast, is drawn to an indwelling catheter which includes a textured portion to allow cells to grow into engagement with the texture during the bodily process of healing the puncture wound caused by insertion of the catheter body into the patient. The purpose of this cell growth is to create a seal between the catheter body and the surrounding bodily tissue at the interface thereby forming a seal against the migration of bacteria and fungi into the vessel.

The texture is not of the type or for the purpose of the Wenstrom, Jr., Hildwein, et al., Wellner, et al., Ternamian, or Bedi devices. Each of the devices of the cited references is designed to create a hole, port, or vent, into a body cavity. The migration of bacteria or fungi into the body of the patient between the device and the surrounding bodily tissue is not a concern since the very purpose of the devices is to create a hole, port, or vent in the context of a sterile surgical environment.

The rejection in the Office action of claims 1 and 5-8 under 35 U.S.C. § 103(a) is believed overcome. Reconsideration and allowance of claims 1 and 5-8 is respectfully requested.

Claims 10-18.

Claims 10-18 are rejected in the Office action under 35 U.S.C. § 103(a) as being unpatentable over Feller, Jr. et al., in view of (1) Hiltenbrandt, (2) Hunt et al., (3) Bedi et al., (4) Ternamian, (5) Wenstrom, Jr., (6) Ciaglia et al., (7) Ju, or (8) O'Conner, et al. Claims 11-18

depend from claim 10. Reconsideration of claims 10-18 is respectfully requested.

Claim 10 has been amended herein to recite “wherein cells grow into engagement with said texture during the bodily process of healing the puncture wound.” Support for this amendment is found on p. 6, ln.17 – p. 7, ln. 1 as recited above.

As stated above, none of the cited references disclose an interface including a texture to allow cells to grow into engagement with the texture. In the Office action, it is admitted that the primary reference, Feller, Jr. et al., *does not disclose* texture on the interface as required by Applicant’s claim 10. Since the Feller, Jr. et al. reference does not disclose texture, it cannot disclose texture to allow cell growth therein.

It is asserted in the *final* Office action that the use of texture on interfaces is conventional in the art as evidenced by the teachings of (1) Hiltenbrandt, (2) Hunt et al., (3) Bedi et al., (4) Ternamian, (5) Wenstrom, Jr., (6) Ciaglia et al., (7) Ju, or (8) O’Conner, et al. Although Applicant respectfully disagrees that these references evidence that the use of texture is conventional in the art, none of these references disclose texture to allow cells to grow into engagement with the texture during the bodily process of healing the puncture wound.

The above cited secondary references disclose various types of constructions used to insert and secure the insertion apparatus to the surrounding tissue, ensuring the stability of the apparatus while conducting *surgical procedures*. As surgical devices, they are not intended to remain in contact with the bodily tissue for a time sufficient for tissue growth therein. Moreover,

their constructions are designed for insertion of the apparatus and are too aggressive for cell growth therein.

Applicant's Claims 10-18 are drawn to an intravenous stent including an interface with texture thereon. The purpose of the textured interface portion is to allow cells to grow into engagement with the texture during the bodily healing process of the puncture wound caused by insertion of the stent. The purpose of this cell growth is to create a seal between the catheter body and the surrounding bodily tissue at the interface thereby forming a seal against the migration of bacteria and fungi into the vessel.

The texture is not of the type or for the purpose of the (1) Hiltenbrandt, (2) Hunt et al., (3) Bedi et al., (4) Ternamian, (5) Wenstrom, Jr., (6) Ciaglia et al. references. Each of the devices of the cited references is designed to create a hole, port, or vent, into a body cavity. The Hiltenbrandt, and Hunt et al., references disclose cannulae for guiding endoscopes for surgical procedures in a body cavity. The Ciaglia et al. device discloses a device for insertion into the peritoneal space for the introduction of pneumoperitoneum and instruments for laproscopic surgery. The Ju and O'Conner, et al. references disclose diagnostic catheter devices. The migration of bacteria or fungi into the body of the patient between the device and the surrounding bodily tissue is not a concern since the very purpose of the devices is to create a hole, port, or vent in the context of a sterile surgical environment.

The Ju and O'Conner references disclose diagnostic catheter devices which each include an elastomeric sleeve which is roughened or knurled to facilitate gripping and rotation thereof using a three-finger catheter engagement. Thus, the alleged "texture" of Ju and O'Conner do not even contact the interface as required by Applicant's claims 10-18. Thus, the devices disclosed in the Ju and O'Conner et al. references include a "textured" surface to be gripped by the surgeon, not to contact the bodily tissue of the patient at the interface as recited in Applicant's claims 10-18.

The rejection in the Office action of claims 10-18 under 35 U.S.C. § 103(a) is believed overcome. Reconsideration and allowance of claims 10-18 is respectfully requested.

Claims 19-21.

In the *final* Office Action, claims 19-21 are rejected under 35 USC § 103(a) as being unpatentable over Feller, Jr. et al. (4,362,156), in view of (1) Wenstrom, Jr., (2) Hildwein, et al., (3) Wellner, et al., (4) Ternamian, or (4) Bedi. Claims 20-21 depend from claim 19. Reconsideration of claims 19-21 is respectfully requested.

Claim 19 has been amended herein to recite that the cannula is frustoconical in shape and "wherein said texture provides friction so as to retain said body in the severed vessel." By way of summary, the device of claims 19-21 is to provide an intravascular device which is frustoconical so that it can be inserted in a severed vessel for the introduction of medication


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therein. In this embodiment of the invention, the texture provides friction so as to retain the device in the vessel. None of the above-cited references disclose an **intravascular device** that is frustoconical in shape and includes texture thereon wherein the texture provides friction to retain the body of the intravascular device in a severed vessel. Accordingly, the rejection is believed overcome. Allowance of claims 19-21 is respectfully requested.

A petition for an extension of time is submitted herewith. If any additional fee is made payable by the filing of this paper, please consider this our authorization to charge the Deposit Account of the undersigned, No. 06-0540.

Respectfully submitted,

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By 
Terry L. Watt, Reg. No. 42,214
Scott R. Zingerman, Reg. No. 35,422
FELLERS, SNIDER, BLANKENSHIP,
BAILEY & TIPPENS, P.C.
321 South Boston, Suite 800
Tulsa, Oklahoma 74103-3318
(918) 599-0621